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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SAUCIER, SANDRA E	

ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
02/03/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/756,368	DOTTORI ET AL.	
	Examiner	Art Unit	
	Sandra Saucier	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *57-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *57-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 57-61 are pending and are considered on the merits.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/13/08 has been entered.

Claim Rejections - 35 USC § 103

Claims 57-61 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Sweeney *et al.* [AW] in combination with US 5,747,536 [AA] and Ogawa *et al.*[U] and Tegos *et al.*[V].

The claims are directed to a method comprising:
adding L-carnitine or an ester of carnitine to a platelet concentrate which has been leukodepleted and suspending the platelet concentrate in the mixture.

The intent of the claimed methods is the suppression of bacterial growth in the platelet concentrate.

Sweeney *et al.* disclose a method of adding L-carnitine or acetyl-carnitine (5mM) to platelet concentrates and agitating the mixture. This is said to reduce glycolysis in the platelet mixture. Glycolysis impairs the quality of the platelet product.

Tegos *et al.* teach that glycolytic enzymes are present in isolated platelets.

Ogawa *et al.* teach the advantages of leukodepleting platelet products with regard to prevention of adverse reactions to PC transfusion and that leukodepleted platelets still possess glycolytic activity.

US 5,747,536 discloses that esters of carnitine other than acetyl ester are known.

The primary reference lacks the disclosure of leukodepleting the platelet concentrate and use of the homologous derivatives of acetyl-carnitine.

The substitution of other esters of carnitine such as butyryl, valeryl, propionyl, isobutyryl for the acetyl ester of carnitine in the method of Sweeney *et al.* would have been obvious when US 5,747,536 was taken with Sweeney *et al.* because US 5,747,536 lists various esters of carnitine and also further discloses the addition of carnitine or its derivatives to platelet concentrates. In the absence of evidence to the contrary, the salts and esters of L-carnitine would reasonably be expected to have a similar activity to L-carnitine or acetylcarnitine because these are simple homologs which may be reasonably expected to have similar properties and activities in the absence of evidence to the contrary.

The substitution of a leukodepleted platelet concentrate for the platelet concentrate of the primary reference would have been obvious because both a nonleukodepleted platelet concentrate and a leukodepleted platelet concentrate comprise platelets, and platelets are known to possess the glycolytic enzymes, see Tegos *et al.* which result in glycolysis during storage. Therefore, even if the leukocytes are removed for advantages known in the art, see Ogawa *et al.*, glycolysis in the preparation would still be expected to occur because platelets perform glycolysis by virtue of having glycolytic enzymes. Thus, the addition of L-carnitine, salts or esters thereof, to a leukodepleted platelet concentrate would be expected to reduce the glycolysis in the platelets and to maintain platelet quality as taught by Sweeney *et al.*.

Although the applicant has recognized another advantage which would flow naturally from following the suggestions of the prior art, this fact cannot be the basis for patentability when the differences would otherwise be obvious.

See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Although the intent of applicant's method is different from the intent of the disclosed method, the active step of adding carnitine or an ester of carnitine in the same concentration is the same. Thus, the results of the method, suppression of bacterial growth, would reasonably be assumed to be the same as the result claimed.

It is not relevant to the analysis of the claimed method that the reference makes no mention of suppressing bacterial growth. Discovery of a new benefit for an old process does not render the old process patentable. *In re* Woodruff, 919 F. 2d 1575, 1578, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). Merely because the reference did not have one of applicant's purposes in mind when the (drug was administered) does not alter the drug's physiological activity. In the context of an anticipation rejection, the Federal Circuit stated, "Where, as here, the result is a necessary consequence of what was deliberately intended, it is of no import that the article's authors did not appreciate the results." Mehl/Biophile Int'l Corp. v. Milgraum, 192 F. 3d 1362, 1366, 52 USPQ2d 1303, 1307 (Fed. Cir. 1999).

See also *In re* Cruciferous Sprout 64 USPQ2d 1202 Fed. Circuit.

One of ordinary skill in the art would have been motivated at the time of invention to make these substitutions in order to obtain the results as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Response to Arguments

Applicant's arguments filed 11/13/08 have been fully considered but they are not persuasive.

Applicant argues that the examiner has not properly examined the present application. Please note that it is not the application which is examined, it is the claims. The examiner contends that the claims have been properly examined, which examination includes parsing the claim language and searching the prior art, and applying the prior art to the claims. Applicant argues that the claimed method is not a discovery of a different biological mechanism, but rather represents a new way to suppress bacterial growth. While this may be true, the active steps of adding the same compound to platelet medium and suspending the platelets in the medium are the same. The only difference in the method being that the platelet composition has been further purified to remove the residual white cells (leukoreduced). Reduction of bacterial contamination would inherently flow from the addition of the carnitine compounds, which addition to platelets is already taught in the prior art. Whether the platelets are more highly purified (leukoreduced) or not does not appear to be an element which would change the known effect of carnitine upon platelets, namely reduction in glycolysis during storage, thereby enhancing storage life of platelet products. That the reference does not reveal that the addition of carnitine also reduces bacterial contamination in the platelets is of little patentable weight since both the effects of bacterial reduction and reduced glycolysis flow directly from the active step of adding of carnitine to the platelets.

Applicant argues that Sweeney *et al.* or US '536 do not disclose that the method disclosed by Sweeney *et al.* would work with leukoreduced platelets. It is correct that the reference of Sweeney *et al.* is not anticipatory. Therefore, indeed, it lacks the disclosure of use of leukoreduced platelets. However, it has been fully explained above that platelets are known have glycolytic enzymes, the functioning of which impairs the quality of the platelets during storage (Sweeney *et al.*) and that glycolysis can be lessened by the addition of carnitine. In the absence of evidence to the contrary, which applicant has not supplied, it is reasonable to assume that platelets are platelets, *i. e.* even if a more purified composition of platelets is used, the result, reduced glycolysis upon the addition of carnitine, would be the same. With regard to the arguments

concerning US '536 disclosing acyl carnitines used for a different purpose, this argument is not persuasive because the reference is merely employed as stated above, to show that various esters of carnitine are known. It is assumed that any ester of carnitine would perform in the same manner as the acetyl ester because these are all homologous compounds, in the absence of evidence to the contrary. Ogawa *et al.* was simply cited as stated above, to show that leukodepletion is a desirable and known process in the art of platelet infusion.

Applicant argues that Ogawa *et al.* do not disclose glycolysis in relation to WBC contamination. Ogawa *et al.* teach that the platelets themselves have the glycolytic enzymes which are the source of the glycolysis during platelet storage. Therefore, whether or not the platelets are further isolated by removal residual white cells, would not appear to effect the fact that the platelets perform glycolysis during storage, which glycolysis is detrimental to the storage stability of the platelets.

Applicant argues that US '536 discloses known acyl derivatives of carnitine being used in a different context. This is true and the reference is employed only to demonstrate that acyl derivatives of carnitine were known at the time of invention.

Applicant argues that Tegos *et al.* teach that "depletion of glycolytic enzymes does not seem to be a major factor in the storage lesion of platelets". Therefore, one of skill in the art would not continue with the method of Sweeney *et al.* or combine these two disclosures. Tegos *et al.* measure the extent of glycolysis during storage of leukoreduced platelets and conclude on page 205 that only modest decreases in glycolytic enzyme activities occur during storage time and that this decrease cannot account for the phenomena known as storage lesion. This finding appears to mesh with the teaching of Sweeney *et al.* who disclose that the quality of platelets stored over time decreases BECAUSE of glycolysis, which according to Tegos *et al.* does not decrease significantly over storage time. There does not appear to be a logical disconnect between these two teachings as urged by applicant. Please note

that Tegos *et al.* clearly teach that leukoreduced platelets still exhibit glycolytic activity.

Applicant argues that he has achieved 8 days of storage of platelets with his invention, which applicant alleges is unexpected. However, the applicant does not limit the claims to the unexpected results. Thus, for at least this reason, the arguments are unpersuasive of error in the rejection.

While including the limitations of the unexpected result are not necessary in the claim language, a claim commensurate in scope to an unexpected result is at the minimum necessary to overcome an obviousness rejection.

See *In re Lindner*, 173 USPQ 356 (CCPA 1972) and *In re Grasselli*, 218 USPQ 769 (Fed. Cir. 1983) which teach that the evidence of nonobviousness should be commensurate with the scope of the claims.

The arguments are not persuasive because the examiner considers the above rejection to disclose all of the elements of the claimed process, *i.e.* all of the active process steps and the product being acted upon AS CLAIMED and the elements are logically and reasonably linked together, which provides motivation for the combination of references.

Conclusion

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (571) 272-0922. The normal work schedule for Examiner Saucier is Monday through Friday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Sandra Saucier/

Primary Examiner
Art Unit 1651